

# **Exhibit 1**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Master File No. 01-CV-12257
	)	Subcategory Case. No. 06-11337
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THIS DOCUMENT RELATES TO:	)	Hon. Patti B. Saris
<i>U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc., et al.</i>	)	
	)	
Civil Action No. 05-11084-PBS	)	
	)	

**DEFENDANTS DEY, INC., DEY, L.P., AND DEY L.P., INC.'S  
REPLY MEMORANDUM IN FURTHER SUPPORT OF THEIR MOTION TO  
EXTEND THE PRODUCTION DEADLINE FOR THE LIMITED PURPOSE OF  
RECEIVING MEDICAID CLAIMS DATA FROM STATES**

Defendants Dey, Inc., Dey, L.P., and Dey L.P., Inc. (collectively, "Dey"), through their undersigned counsel, respectfully submit this reply memorandum in further support of their motion to extend the discovery deadline for the sole purpose of receiving Medicaid claims data from certain individual states.

Plaintiff repeatedly informed Dey that it would produce state claims data and Dey relied on that representation. When Plaintiff finally informed Dey at the November 13, 2008 status conference that it did not intend to produce any additional claims data, Dey promptly issued subpoenas to the remaining states. Now, Dey seeks permission to receive state Medicaid claims data produced by states after the December 15th cut-off in response to its subpoenas and Plaintiff objects. The objection is without merit.

The claims data is necessary to determine which claims, if any, were paid allegedly using Dey's AWPs and WACs. The state claims data which Dey subpoenaed is also needed to rebut Plaintiff's expert opinion. Plaintiff apparently believes that state claims data is

not necessary for its expert to make a damages analysis and intends to rely on CMS data. Dey requires state claims data in order to demonstrate that Plaintiff's approach to damages and reliance on the CMS data is fundamentally flawed. Expert discovery is not scheduled to close until May 22, 2009. Allowing states to produce claims data does not require an extension of any other deadline.

**I. THE CLAIMS DATA AVAILABLE FROM THE CMS WEBSITE IS INSUFFICIENT**

Plaintiff argues that Dey has "access to substantial Medicaid data via a public website maintained by the Center for Medicare and Medicaid Services (CMS)." This data is inadequate. The data publicly available from CMS includes two categories of data, SDUD data and MAX/SMRF data. SDUD data is inadequate because it does not show whether Dey's AWP or WAC were actually used to pay claims; the data subpoenaed from the states will show this. Though MAX/SMRF data has some claims level data, it is not available for all states prior to 1999,<sup>1</sup> and does not include quantity for any state prior to 1996. MAX/SMRF also does not include dispensing fee and co-payments, which reduces the precision of attempts to calculate the reimbursement basis. MAX/SMRF data is also rounded, which further reduces the precision of payment basis analysis. Due to these deficiencies, it is not possible to determine how claims were actually paid – a calculation that can be performed using state claims data. *See Declaration of Damon Suden, dated January 5, 2009 ("Suden Decl."), ¶¶ 4 - 11, Exhibit A.* The reimbursement basis is crucial to Dey's damages analysis. Since Plaintiff has alleged only that it has suffered damages as a result of AWPs and WACs reported by Dey, Dey cannot be liable for any claims not reimbursed on the basis of Dey's reported AWPs or WACs. *See State of*

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<sup>1</sup> The following states covered by Dey's motion have no MAX/SMRF data prior to 1999: Arizona, Connecticut, Illinois, Maine, Maryland, Massachusetts, Nevada, North Carolina, Oklahoma, Oregon, South Carolina, South Dakota, Virginia, and West Virginia. The following states covered by Dey's motion have incomplete MAX/SMRF data for the years 1996 to 1999: Colorado, Florida, and Michigan.

*California v. Abbott Labs., Inc.*, No. 03-CV-2238, Memorandum and Order dated 3/22/07 at 30-32.

In several instances, there are discrepancies between a state's reimbursement policies and that state's actual reimbursement practices — and this also cannot be determined from the CMS data, but only from the state claims data. For example, from July 2000 to April 2002, WAC was "removed from [Florida's reimbursement] logic" due to an alleged "erroneous computer programming change." *See* Suden Decl., Exhibits B, C; *see also* Florida Second Amended Complaint at ¶¶ 32-33.

At least two states used reimbursement formulas that conflict with their state plans. Throughout the relevant time period, Massachusetts used AWP less a percentage as a "proxy" for WAC in instances where a WAC was not reported, but failed to include this policy in its State Plan Amendment or otherwise inform Defendants of this policy. *Commonwealth of Massachusetts v. Mylan Labs, et al.*, Civil Action No. 03-11865-PBS, December 23, 2008 Order at 9-10, 42-43. Similarly in Hawaii after 2001, in instances where there was a FUL for a drug that was higher than the state MAC, it was Hawaii's practice to reimburse at the higher FUL. *See* Suden Decl., Exhibit D. This is contrary to Hawaii's State Plan, which provided for reimbursement at "the lower of" billed charges, the provider's usual and customary charge, estimated acquisition cost, FUL or the State MAC. *See* Suden Decl., Exhibit E at 4(a)2. Some states did not consider WAC or AWP at all in calculating reimbursement for at least some claims. For example, in Alaska prior to May 2003 for any drug with a FUL, Alaska's "payment methodology...failed to incorporate" AWP, but would instead reimburse at the lower of the FUL or the billed charge. *See* Suden Decl., Exhibit F.

These issues directly impact both liability and any damages analysis. Indeed, without incorporating the information from the state claims data, any attempt to calculate damages would be fundamentally flawed. Moreover, Dey should not be held liable for any claims not reimbursed on the basis of Dey's AWP or WAC. If complete state claims data is not produced, Dey intends to move to preclude Plaintiff from seeking damages based on those states. For claims reimbursed on a basis other than AWP or WAC, there should be no liability.

**II. AN EXTENSION OF THE PRODUCTION DEADLINE FOR THE LIMITED PURPOSE OF RECEIVING CLAIMS DATA FROM STATES WOULD NOT REQUIRE AN EXTENSION OF ALL DEADLINES**

Plaintiff's opposition to Dey's motion is also logically inconsistent. Plaintiff argues both that "the [state claims] data that has been produced is sufficient" and that "[i]t is obvious that any new state claims data would need to be analyzed and evaluated by the United States' damages expert." Opp. at 5. Plaintiff has chosen to rely on the data available on the CMS website and the incomplete state claims data produced to date for its own damages analysis. That choice cannot bar Dey from obtaining independent evidence that demonstrates that the Plaintiff's expert opinion is wrong.

Moreover, given Plaintiff's position that it has sufficient data to complete its expert report, the additional state claims data which Dey hopes to receive will be used to rebut Plaintiff's damages report and demonstrate its flaws. Therefore, production of additional state claims data is both vital to Dey's defense and will not require an extension of any expert disclosure deadlines.

**CONCLUSION**

For the above reasons, Dey respectfully requests that this motion be granted, and an Order be entered extending the production deadline for any states which have not yet produced complete Medicaid claims data.

Dated: January 6, 2009

Respectfully Submitted,

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